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EXAMINER
ROARK, JESSICA H

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/383,551	Applicant(s) TAMATANI ET AL.	
	Examiner Jessica H. Roark	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2003 and 13 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-214* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-214* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 August 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *36* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

RESPONSE TO APPLICANT'S AMENDMENT

1. Claims 37-214 are pending and under consideration in the instant application.

2. Applicant's IDS, filed 2/11/03 (Paper No. 36), is acknowledged.

3. This Office Action will be in response to applicant's arguments, filed 2/13/03 (Paper No. 39). The rejections of record can be found in the previous Office Action (Paper No. 34).

It is noted that New Grounds of Rejection are set forth herein.

4. Priority: Acknowledgment is again made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

5. The Declaration of Dr. Katsunari Tezuka, filed 2/11/03 (Paper No. 37) stating that neither the poster presented at the Kyoto International Conference Hall, Takaragaike Sakyo-ku, Kyoto, Japan on November 30, 1994 (IDS # AQQ) nor another poster displayed November 18, 1993, for which no paper copy was retained, were distributed to the organizer or attendees of the conferences is acknowledged.

Claim Rejections – 35 U.S.C. §§ 102 and 103

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 115-116, 118-120 and 133-136 are rejected under 35 U.S.C. 102(b) as being anticipated by either
Tamatani et al. (Proceedings of the Japanese Society Immunology 1993; Vol 23, Abstract No. H-160, IDS #AWW, see entire Abstract) *or*
Tamatani et al. (Proceedings of the Japanese Society Immunology 1994; Vol 24, Abstract No. W17-14, IDS #AXX, see entire Abstract),
each as evidenced by Tamatani et al. (Int. Immunol. 2000 ; 12(1):51-55, IDS #AJ) and Tezuka et al. (Biochem. Biophys Res. Com. 2000; 276:335-345, IDS # AK).

Tamatani et al. (1993) teach a mouse monoclonal antibody that binds a 47 kDa homodimeric rat polypeptide composed of two peptide chains of about 24 and 28 kDa and expressed on activated rat lymphocytes and thymocytes, and that aggregated (i.e., mediates adhesion of) rat lymphoid cells (see in particular "Results and Considerations").

Tamatani et al. (1993) teach that the mouse monoclonal antibody was produced by immunizing a mouse with the rat thymoma cell strain FTL435, then fusing lymph node cells with mouse myeloma cells (e.g., see "Method").

Tamatani et al. (1994) teach the JTT-1 antibody and that this antibody binds an antigen expressed by a 0.9 kb gene isolated from a rat Con A blasts (see entire Abstract, especially "Results and Considerations"). Tamatani et al. (1994) also teach the isolation and N-terminal sequencing of the JTT-1 antigen from FTL435 cells (see "Methods" section), and that the antigen encoded by the 0.9 kb gene and that recognized by the JTT-1 antibody on FTL435 cells have the same N-terminal sequence. Tamatani et al. (1994) also teach that binding of the JTT-1 antibody is detected with an anti-mouse antibody (Methods); therefore the JTT-1 antibody is a mouse anti-rat antibody.

Tamatani et al. (2000) evidence that the cell surface molecule expressed by the rat thymoma cells FTL435 and having the properties set forth supra is rat AILIM/ICOS (see entire document, but especially "Results and Discussion, pages 52-55).

Tezuka et al. evidence that there are two forms of rat AILIM/ICOS polypeptide which differ only in their cytoplasmic domains and have the amino acid sequences set forth in SEQ ID NO:13 and SEQ ID NO:15 (see entire document, especially Figure 1).

The antibody of Tamatani et al. (1993) and the JTT-1 antibody of Tamatani et al. (1994) each bound the AILIM/ICOS cell surface molecule expressed by FTL435 thymoma cells. The antibody taught by each Tamatani et al. reference must therefore bind the extracellular domain of the AILIM/ICOS polypeptide. Although SEQ ID NO:13 is one of two forms to AILIM/ICOS expressed by rat cells, the two forms of AILIM/ICOS do not differ in the amino acid sequence of their extracellular domains.

Therefore, the antibody taught by each of Tamatani et al. (1993) and Tamatani et al. (1994) is a mouse monoclonal antibody that binds the extracellular region of a polypeptide consisting of SEQ ID NO:13.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the antibody taught by Tamatani et al. (1993).

The reference teachings thus anticipate the instant claimed invention.

8. It is noted that Sakamoto et al. (Hybridoma and Hybridomics 2001; 20(5):293-303) teach that the mouse anti-rat AILIM/ICOS antibodies JTT.1 and JTT.2 do not bind to human or mouse AILIM/ICOS (see especially Figure 1).

Thus the teachings of Tamatani et al. (Proceedings of the Japanese Society Immunology 1993; Vol 23, Abstract No. H-160, IDS #AWW) do not appear to anticipate claims limited to antibodies to the human AILIM/ICOS polypeptide of SEQ ID NO:2, or claims limited to antibodies to the mouse AILIM/ICOS polypeptide of SEQ ID NO:14.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 115, 117, 124 and 126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tamatani et al. (Proceedings of the Japanese Society Immunology 1993; Vol 23, Abstract No. H-160, IDS #AWW, see entire Abstract) as evidenced by Tamatani et al. (Int. Immunol. 2000 ; 12(1) :51-55, IDS #AJ) and Tezuka et al. (Biochem. Biophys Res. Com. 2000; 276:335-345, IDS # AK), in view of Goding (Monoclonal Antibodies: Principles and Practice, Second Edition, Academic Press, Orlando, Florida 1986, Chapter 8, pages 281-293).

The claims are drawn to non-hamster polyclonal antibodies that bind a polypeptide consisting of SEQ ID NO:13, and to pharmaceutical compositions comprising said antibodies.

Tamatani et al. (1993) as evidenced by Tamatani et al (2000) and Tezuka et al. have been discussed supra and teach a mouse monoclonal antibody that binds the extracellular region of a polypeptide consisting of SEQ ID NO:13.

The teachings of Tamatani et al. (1993) as evidenced by Tamatani et al (2000) and Tezuka et al. differ from the instant claims by not teaching a polyclonal antibody or pharmaceutical composition comprising.

Goding reviews methods of making polyclonal antibodies and the desirability of polyclonal antibodies for detecting an antigen of interest, particularly when the antigen was not in its native conformation (see chapter 8). As taught by Goding (see especially the Introduction on pages 281-282), it was well known in the art at the time the invention was made that even when a monoclonal antibody to a particular antigen was available, it was still desirable to also provide polyclonal antibodies to the same antigen. Goding also teaches that polyclonal antibodies may be formulated as a preparation in serum (e.g., page 288), or purified and stored in Tris-HCl (page 289), each of which is a pharmaceutically acceptable carrier.

Thus it would have been obvious to the ordinary artisan at the time the invention was made to prepare a polyclonal antibody to a polypeptide consisting of SEQ ID NO:13. The ordinary artisan would have been motivated to provide polyclonal antibodies to a polypeptide consisting of SEQ ID NO:13 because polyclonal antibodies were better suited for use in immunoassays involving loss of the native conformation of the antigen (e.g., western blotting; see in particular comment at 3rd paragraph, page 281) and reagents detecting the non-native conformation of the polypeptide of SEQ ID NO:13 would have facilitated the biochemical characterization of the newly identified adhesion molecule taught by Tamatani et al. (1993).

Given the simplicity of the method of preparing polyclonal antibodies by immunizing any of a number of species, as reviewed by Goding in chapter 8, and the availability of antigen affinity purified by immunoprecipitation with the monoclonal antibody of Tamatani et al.; the ordinary artisan at the time the invention was made would have had a reasonable expectation of producing a non-hamster polyclonal antibody that bound the polypeptide consisting of SEQ ID NO:2. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

11. Claims 115-116, 118-120, 124-125 and 127-129 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tamatani et al. (Proceedings of the Japanese Society Immunology 1993; Vol 23, Abstract No. H-160, IDS #AWW, see entire Abstract) as evidenced by Tamatani et al. (Int. Immunol. 2000 ; 12(1) :51-55, IDS #AJ) and Tezuka et al. (Biochem. Biophys Res. Com. 2000; 276:335-345, IDS # AK), in view of Harlow and Lane (Antibodies: A Laboratory Manual, Cold Spring Harbor Laboratory, 1988, page 285).

The claims are drawn to pharmaceutical compositions comprising non-hamster antibodies that bind a polypeptide consisting of SEQ ID NO:13, including monoclonal antibodies and monoclonal antibodies that bind the extracellular region of the polypeptide of SEQ ID NO:13.

Tamatani et al. (1993) as evidenced by Tamatani et al (2000) and Tezuka et al. have been discussed supra and teach a mouse monoclonal antibody that binds the extracellular region of a polypeptide consisting of SEQ ID NO:13.

The teachings of Tamatani et al. (1993) as evidenced by Tamatani et al (2000) and Tezuka et al. differ from the instant claims by not explicitly teaching a pharmaceutical composition comprising the antibody in a pharmaceutically acceptable carrier.

However, Harlow and Lane teach that formulation of monoclonal antibodies as pharmaceutical compositions comprising a pharmaceutically acceptable carrier such as PBS for storage and immunoassays was well known in the art at the time the invention was made (see page 285, Harlow, 1988).

Therefore, it would have been obvious to the ordinary artisan at the time the invention was made to place the monoclonal antibody taught by Tamatani et al. (1993) in a pharmaceutically acceptable carrier such as PBS for storage and for use in immunoassays such as those taught by Tamatani et al. The ordinary artisan would have been motivated to place the antibody of Tamatani et al. (1993) in a carrier such as PBS because PBS and other pharmaceutically acceptable carriers offered a formulation that could be used in any desired application. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. Claims 155, 157-160 and 162-164 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tamatani et al. (Proceedings of the Japanese Society Immunology 1994; Vol 24, Abstract No. W17-14, IDS #AXX, see entire Abstract) as evidenced by Tamatani et al. (Int. Immunol. 2000 ; 12(1) :51-55, IDS #AJ) and Tezuka et al. (Biochem. Biophys Res. Com. 2000; 276:335-345, IDS # AK), in view of Tedder et al. (U.S. Pat. No. 5,484,892).

The claims are drawn to a process for producing a cell which secretes an antibody that binds a polypeptide consisting of SEQ ID NO:13, as well as to methods of producing the antibody by culturing said cell.

Tamatani et al. (1994) teach the identification of a 0.9 kb gene encoding the antigen recognized by the JTT.1 antibody and expression of the protein from the 0.9 kb gene (see entire Abstract, especially "Results and Considerations"). Tamatani et al. (1994) also teach the isolation and N-terminal sequencing of the JTT.1 antigen from FTL435 cells (see "Methods" section).

Tamatani et al. (2000) evidence that the cell surface molecule recognized by the JTT-1 antibody is rat AILIM/ICOS (see entire document, but especially "Results and Discussion, pages 52-55).

Tezuka et al. evidence that there are two forms of rat AILIM/ICOS polypeptide which differ only in their cytoplasmic domains and have the amino acid sequences set forth in SEQ ID NO:13 and SEQ ID NO:15 (see entire document, especially Figure 1).

Tamatani et al. (1994) as evidenced by Tamatani et al. (2000) and Tezuka et al. differ from the instant claims by not teaching a method of producing a cell which secretes an antibody that binds a polypeptide consisting of SEQ ID NO:13 or methods of producing the antibody by culturing said cell.

However, methods of producing a cell that secreted an antibody to a protein of interest, and of producing the antibody produced by that cell were well known in the art at the time the invention was made.

For example, Tedder et al. teach that a panel of cells secreting antibodies to the cell adhesion antigen CD22 could be made by immunizing a mammal with a recombinant cell transfected with a cDNA encoding the antigen, obtaining from the immunized animal cells that secrete antibodies and identifying those cells that secrete an antibody specific for the CD22 antigen (see especially column 4 at line 30 to column 5 at line 44).

Tedder et al. also teach that purified antigen, rather than recombinant cells transfected with a cDNA encoding the antigen, could be used as the immunogen (see e.g., column 4 at lines 45-49).

Tedder et al. further teach that the antibody secreted by the cell could be produced by culturing the cell and collecting the antibody from the cell culture (e.g., column 5 at lines 21-28).

Tedder et al. also teach that even when an antibody has been produced to an antigen, the ordinary artisan would nevertheless be motivated to provided additional antibodies to the same antigen in order to further characterize the antigen, to provide antibodies that blocked a function of the antigen such as cell adhesion, and to provide yet other antibodies which bound the antigen but did not block a particular function of the antigen (see entire document, but especially comments at column 8 and the Table at column 9).

Therefore, it would have been obvious to the ordinary artisan at the time the invention was made to use the art-recognized methods as exemplified by Tedder et al. to produce additional cells secreting antibodies to the JTT-1 antigen taught by Tamatani et al. (1994) and isolate the antibody secreted by the cells. Tedder et al. exemplify that a process for producing cells that secreted an antibody to any antigen of interest, including transmembrane cell adhesion molecules, was well known in the art at the time the invention was made.

Given the teachings of Tamatani et al. of both purified antigen and recombinant antigen encoded by an isolated gene; the ordinary artisan would have had a reasonable expectation that the instantly recited processes could be applied to either the isolated polypeptide or a recombinant cell, and that a non-rat mammal, including a mouse or hamster, could be immunized and antibody-secreting cells isolated.

Tedder et al. also show that the ordinary artisan, given the JTT-1 antigen and a single antibody to that antigen, would have been motivated to provide a process for producing cells that secreted additional antibodies to the JTT-1 antigen so that antibodies having different functional properties could be obtained and used to further characterize the antigen or block its cell adhesion function.

An antibody produced by immunizing with a recombinant cell transfected with the cDNA of Tamatani et al (1994) must bind the extracellular domain of the AILIM/ICOS polypeptide because the cytoplasmic domain would be intracellular and so not immunogenic. In addition, although SEQ ID NO:13 is one of two forms to AILIM/ICOS expressed by rat cells, the two forms of AILIM/ICOS do not differ in the amino acid sequence of their extracellular domains; thus irrespective of which form of AILIM/ICOS was contained in the 0.9 kb gene of Tamatani et al. (1994), an antibody produced by immunizing with a recombinant cell transfected with the 0.9 kb gene would bind the extracellular domain of SEQ ID NO:13.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Applicant's statement in the Remarks filed 2/13/03 and in the Statement filed under 37 CFR 1.78(c) on 2/13/03 that the present application (USSN 09/383,551), USSN 09/830,548 and USSN 09/859,053 were each owned or subject to an obligation of assignment to Japan Tobacco Inc. is acknowledged.

15. Applicant's comments in the Remarks filed 2/13/03 regarding withdrawal of all provisional obviousness-type double patenting rejections when a provisional obviousness-type double patenting rejection is the only rejection remaining are acknowledged.

However, in view of the rejections set forth supra, a provisional obviousness-type double patenting rejection is not the only rejection remaining; thus the provisions of MPEP 804.I.B do not at present apply.

The following provisional obviousness-type double patenting rejections are therefore appropriate until such time as no other outstanding rejections remain, or until their conversion to non-provisional rejections.

16. The indicated allowability of claims 55-72 and 90-99 is withdrawn in view of the amendment to claims 1-7, 10-15, 18-22 and 25-30 of copending Application No. 09/830,548 and the newly discovered copending application No. 10/301,056. Provisional rejections based on the newly cited references follow.

17. Claims 55-72 and 90-99 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 10-15, 18-22 and 25-30 of copending Application No. 09/830,548 (as amended to recite method claims) as evidenced by the sequence listing of WO98/38216 (of record). Although the conflicting claims are not identical, they are not patentably distinct.

The instant claims are drawn to method of inhibiting activation of lymphocytes (claims 55-63 and 90-94) or methods of treating glomerulonephritis (claims 64-72 and 95-99) by administering antibodies in various forms to the polypeptide of SEQ ID NO:2, which is a human JTT antigen polypeptide.

Claims 7, 15, 22 and 30 of copending Application No. 09/830,548 recite various methods comprising administering "antibodies which bind AILIM" (claims 1-6, 10-14, 18-21 and 25-29). Although claims 1, 10, 18 and 22 recite methods comprising administering a substance which modulates signal transduction mediated by AILIM generically, antibodies to AILIM are obvious embodiments of the generic claims, in view of the recitation of antibodies in claims 7, 15, 22 and 30.

Copending Application No. 09/830,548 does not recite methods comprising administering antibodies to SEQ ID NO:2, nor does it recite antibodies in the various forms recited in the instant claims.

However, copending Application No. 09/830,548 defines "AILIM" on page 17 at lines 13-30 to mean human AILIM/JTT-1 antigen of SEQ ID NO:1 of WO98/38216. The amino acid sequences set forth as encoded by the cDNA of SEQ ID NO:1 of WO98/38216 is the same as instant SEQ ID NO:2, as evidenced by the Sequence Listing of WO98/38216.

Therefore, although antibodies to the polypeptides of the instant SEQ ID NOS are not explicitly recited in the claims of copending Application No. 09/830,548; they nevertheless are obvious embodiments of the recited invention. In view of claims 1-7, 10-15, 18-22 and 25-30 of copending Application No. 09/830,548, as evidenced by WO98/38216, an antibody to the human AILIM polypeptide is an antibody to the polypeptide of SEQ ID NO:2.

In addition, the ordinary artisan would have found it obvious to produce antibodies in any of a variety of art-recognized forms for use in the instantly recited methods. The ordinary artisan would have been motivated to produce chimeric, humanized, or human antibodies in particular, because pharmaceutical compositions for use in humans optimally employ antibodies in these forms. In view of the definition of AILIM in copending Application No. 09/830,548 as evidenced by WO98/38216, the ordinary artisan would have been motivated to produce antibodies to SEQ ID NO:2 because it was the known AILIM polypeptide. In the absence of guidance to production of only hamster antibodies, the antibodies of copending Application No. 09/830,548 necessarily include non-hamster antibodies, e.g., a human antibody. Further, the ordinary artisan would have been motivated to select antibodies which bind the extracellular domain of the polypeptide because AILIM is a cell surface protein.

Finally, although the instant methods are drawn to "inhibiting activation of lymphocytes" and "treating glomerulonephritis" and these methods are not explicitly recited in copending Application No. 09/830,548; inhibition of lymphocyte activation would necessarily occur when an anti-AILIM antibody was administered as recited in any of the methods of USSN 09/830,548. In addition, claims 10-15 of USSN 09/830,548 recite a method of treating inflammation and the specification of USSN 09/830,548 discloses that "inflammation" includes glomerulonephritis (page 13 at lines 8-23). Thus the instantly claimed methods are either inherent in, or an obvious variant of, the methods recited in claims 1-7, 10-15, 18-22 and 25-30 of copending Application No. 09/830,548, as amended.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. Claims 37-38, 40-42, 45-47, 49-51, 54, 73-76, 79-81, 84-86, 89, 100-101, 104-108, 110-113, 115-116, 118-120, 123-125, 127-129, 132-136, 139-141, 144-146, 149-151, 154-158, 160-163, 165-166, 168-170, 173-175, 177-179, 182-186, 189-191, 194-196, 199-201, 204-208, 210-213 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25-39 and 109-315 of copending Application No. 09/859,053 (as amended) as evidenced by the sequence listing of WO98/38216 (of record). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant claims are drawn to antibodies in various forms to polypeptides identified by individual SEQ ID NOS that are human, rat and mouse JTT antigen polypeptides, as well as to cells producing said antibodies and pharmaceutical compositions comprising.

Claims 25-39 and 109-315 of copending Application No. 09/859,053 recite in various forms human antibodies which bind an AILIM polypeptide, cells producing such antibodies and pharmaceutical compositions of said antibodies. The claims of copending Application No. 09/859,053 recite both the genus of human antibodies to an AILIM polypeptide, and species that are particular human antibodies of AILIM (including the DNA encoding and cells producing).

Copending Application No. 09/859,053 does not recite antibodies to particular SEQ ID NOS, nor does it recite antibodies in the various forms recited in the instant claims.

However, copending Application No. 09/859,053 defines "AILIM" page 59 line 30 to page 60 line 7 to mean the human, rat, rat variant or mouse polypeptides found in WO98/38216. The human AILIM/JTT-1 antigen encoded by SEQ ID NO:1; rat AILIM/JTT-1 antigen encoded by SEQ ID NO:4 or 6; and mouse AILIM/JTT-1 antigen encoded by SEQ ID NO:5 of WO98/38216 are the same as instant SEQ ID NOS:2, 13, 14 and 15, respectively, as evidenced by the Sequence Listing of WO98/38216.

Therefore, although antibodies to the polypeptides of the instant SEQ ID NOS are not explicitly recited in the claims of copending Application No. 09/859,053; they nevertheless were obvious embodiments of the recited invention. The ordinary artisan would clearly have been motivated to produce human antibodies to at least the polypeptide of instant SEQ ID NO:2 (human AILIM) in order to have a reagent that could be used in methods of treating humans. In addition, human antibodies produced to the human AILIM polypeptide of SEQ ID NO:2 would also bind the rat and mouse AILIM molecules of instant SEQ ID NOS:13-15 because of the numerous shared epitopes between SEQ ID NO:2 and the mouse and rat sequences. Further, the species of human antibodies to human AILIM recited in the claims of copending application 09/859,053 anticipate claims to non-hamster antibodies to the various polypeptides, since a human antibody is a non-hamster antibody. Claims reciting cells producing such antibodies also render obvious the human antibodies produced, since the purpose of the cells is to produce the human antibody. Finally, methods of making human antibodies as recited were well known in the art at the time the invention was made, and obvious in view of any teaching to make human antibodies using particular polypeptides.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. Claims 37-214 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 7, 9, 11-13, 16, 18-22, 26-27, 29, 31-33 and 36 of copending Application No. 10/301,056. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant claims are drawn to antibodies in various forms to polypeptides identified by individual SEQ ID NOS that are human, rat and mouse JTT antigen polypeptides, as well as to pharmaceutical compositions comprising said antibodies, methods of inhibiting activation of lymphocytes (claims 55-63 and 90-94) or of treating glomerulonephritis (claims 64-72 and 95-99) comprising administering said antibodies.

Claim 1 of USSN 10/301,056, and claims dependent thereon, recites a pharmaceutical composition comprising a drug that regulates the function of a JTT-1 antigen. The specification of USSN 10/301,056 on pages 114-116 disclose that an antibody is such a drug.

Claim 18 of USSN 10/301,056, and claims dependent thereon, recites methods of treating a disease, including an inflammatory disease, by administering a pharmaceutical composition of claim 1.

USSN 10/301,056 does not explicitly recite the various forms of antibodies recited in the instant claims, nor does it explicitly recite methods of inhibiting activation of lymphocytes or methods of treating glomerulonephritis by administering said antibodies.

However, the ordinary artisan would have found it obvious to produce antibodies in any of a variety of art-recognized forms for use in the instantly recited methods and formulate them as pharmaceutical compositions. Methods of making various forms of antibodies, including making the cells which produce the antibodies, were well known to the ordinary artisan at the time the invention was made. The ordinary artisan would have been motivated to produce chimeric, humanized, or human antibodies in particular, because pharmaceutical compositions for use in humans optimally employ antibodies in these forms. The ordinary artisan would have been motivated to produce antibodies to SEQ ID NOS:13-15 because they the JTT polypeptides of mouse and rat and antibodies to the polypeptides of these different species were applicable in disease model systems for evaluating pharmaceutical compositions comprising antibodies to human JTT. In the absence of guidance to production of only hamster antibodies, the antibodies of copending Application No. 10/301,056 necessarily include non-hamster antibodies, e.g., a human antibody. Further, the ordinary artisan would have been motivated to select antibodies which bind the extracellular domain of the polypeptide because JTT is a cell surface protein. Thus the instantly recited antibodies, cells producing them and methods of making them are obvious embodiments of the pharmaceutical composition recited in copending Application No. 10/301,056.

Finally, although the instant methods are drawn to "inhibiting activation of lymphocytes" and "treating glomerulonephritis" and these methods are not explicitly recited in copending Application No. 10/301,056; inhibition of lymphocyte activation would necessarily occur when an anti-JTT antibody was administered as recited in the methods of USSN 10/301,056. The specification of USSN 10/301,056 on pages 71 and 103-105 discloses that glomerulonephritis is an inflammatory disease treatable by administration of an antibody to JTT antigen. Thus the instantly claimed methods are either inherent in, or an obvious variant of, the methods recited in copending Application No. 10/301,056.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

20. Claims 37-214 are directed to an invention not patentably distinct from claims 1, 4-5, 7, 9, 11-13, 16, 18-22, 25-27, 29, 31-33 and 36 of commonly assigned Application No. 10/301,056 for the reasons set forth supra.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned Application No. 10/301,056, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Conclusion

21. No claim is allowed.

22. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 2/11/03 prompted the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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Technology Center 1600
May 6, 2003

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PRIMARY EXAMINER
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5/9/03